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IDS #3  
4-23-053  
A-803IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Tiansheng, et al.

Serial No.: 09/945,517

Group Art Unit No.:

Filed: 08/30/2001

Examiner:

For: L-Methionine as a Stabilizer for NESP/EPO in HSA-Free Formulations

Docket No.: A-803

TECH CENTER 1600/2900

APR 19 2002

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INFORMATION DISCLOSURE STATEMENTAssistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

As a means of complying with the duty of disclosure, applicant(s) submit(s) a "List of References Cited by Applicant" on a modified PTO-1449 form and provide(s) a copy of each of the listed references for consideration by the Examiner.

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under section 1.114, whichever event occurs last. 37 CFR 1.97(b).

Applicant(s) request(s) consideration of this information and passage of the application to issue.

The Commissioner is hereby authorized to charge any filing fees which may be required or credit any overpayment to Deposit Account No. 01-0519 in the name of Amgen Inc.

Respectfully submitted,

Craig A. Crandall  
Attorney/Agent for Applicant(s)  
Registration No.: 38,416  
Phone: (805) 447-3011  
Date: April 16, 2002

Please send all future correspondence to:

US Patent Operations/ CAC  
Dept. 4300, M/S 27-4-A  
AMGEN INC.  
One Amgen Center Drive  
Thousand Oaks, California 91320-1799

## EXPRESS MAIL CERTIFICATE

\*Express Mail\* mail labeling number: EL360687647US

Date of Deposit: April 16, 2002

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Lynne Buchsbaum  
Printed Name



Modified Form PTO-1449

### LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

Sheet 1 Of

09/945.517

Atty. Docket No.

A-803

Applicant

Tiansheng, et al.

Filing Date

08/30/2001

Group

1653

TECH CENTER 1600/290

APR 16 2002

### U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
HS	A1	4,667,016	May 19, 1987	Lai	530	397	
HS	A2	4,695,623	Sep 22, 1987	Stabinsky	530	351	
HS	A3	4,703,008	Oct 27 1987	Lin	435	240	
HS	A4	4,810,643	Mar 7, 1989	Souza	435	68	
HS	A5	4,897,471	Jan 30, 1990	Stabinsky	536	27	
HS	A6	4,999,291	Mar 12, 1991	Souza	435	69.1	
HS	A7	5,075,222	Dec 24, 1991	Hannum	435	69.1	
HS	A8	5,272,135	Dec 21, 1993	Takruri	514	12	
HS	A9	5,372,808	Dec 13, 1994	Blatt	424	85.4	
HS	A10	5,441,868	Aug 15, 1995	Lin	435	69.4	
HS	A11	5,541,293	Jul 30, 1996	Stabinsky	530	351	
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HS	A13	5,581,476	Dec 3, 1996	Osslund	364	496	
HS	A14	5,582,823	Dec 10, 1996	Souza	424	85.2	
HS	A15	5,618,698	Apr 8, 1997	Lin	435	69.4	
HS	A16	5,621,080	Apr 15, 1997	Lin	530	350	
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EXAMINER:

Date Considered:

10-10-03

EXAMINER: Initial if citation considered; whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Modified Form PTO-1449

Atty. Docket No.

A-803

Serial No.

09/945.517

Applicant

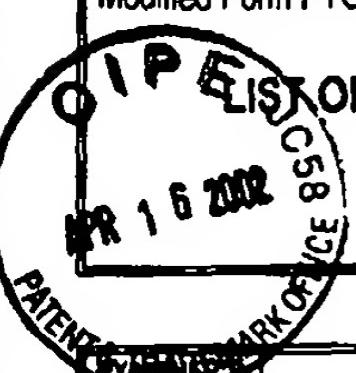
Tiansheng, et al.

Filing Date

08/30/2001

Group

1653



## FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	PLACE	CID. CLASS	TRANSMISSION YES NO
X3	B1 WO 91/05795	15 Oct 1992	PCT	C07K	3/18	
X3	B2 WO 92/17505	28 Apr 1994	PCT	C07K	15/28	
X3	B3 WO 94/09257	4 Aug 1994	PCT	E21D	9/08	
X3	B4 WO 94/17185	2 May 1991	PCT	C12N	15/27	
X3	B5 WO 95/17206	29 Jun 1995	PCT	A61K	38/18	
X3	B6 WO 95/26746	12 Oct 1995	PCT	A61K	38/16	
X3	B7 WO 96/05309	22 Feb 1996	PCT	C12N	15/12	
X3	B8 WO 96/40912	19 Dec 1996	PCT	C12N	15/12	
X3	B9 WO 97/00128	3 Jan 1997	PCT	B01J	—	
X3	B10 WO 97/01010	9 Jan 1997	PCT	E05B	65/19	
X3	B11 WO 97/06816	27 Feb 1997	PCT	A61K	38/17	
X3	B12 WO 97/23614	3 Jul 1997	PCT	C12N	15/12	
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Date Considered:

10-10-03

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APRIL 19 2002  
O 1653

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## LIST OF REFERENCES CITED BY APPLICANT

APR 16 2002  
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EXAMINER'S OFFICE  
PATENT & TRADEMARKS

(Use several sheets if necessary)

Atty. Docket No.	A-803	Serial No.	09/945.517
Applicant	Tiansheng, et al.		
Filing Date	08/30/2001	Group	1653

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

X5	C1	Miyake et al., "Purification of Human Erythropoletin", <i>Journal of Biological Chemistry</i> , Vol. 252, (15), pp. 5558-5564, (1977)
X5	C2	Lai, et al., "Structural Characterization of Human Erythropoietin", <i>The Journal of Biological Chemistry</i> , Vol. 261(7), pp. 3116-3121, (1986)
X5	C3	Brody, et al., "Recombinant Human Erythropoletin: Purification and Analysis of Carbohydrate Linkage", <i>Archives of Biochemistry and Biophysics</i> , Vol. 265(2), pp.329-336, (1988)
X5	C4	Dube, et al., "Glycosylation at Specific Sites of Erythropoletin Is Essential for Biosynthesis, Secretion, and Biological Function", <i>The Journal of Biological Chemistry</i> , Vol. 263 (33), pp. 17516-17521, (1988)
X5	C5	DeLorme, et al., "Role of Glycosylation on the Secretion and Biological Activity of Erythropoietin", <i>Biochemistry</i> , Vol. 31, pp. 9871-9876 (1992)
X5	C6	Egrie, et al., "The Role of Carbohydrate on the Biological Activity of Erythropoletin", <i>Glycoconjugate Journal</i> , Vol. 10, pp. 263 (1993)
X5	C7	Markham, et al., "Epoetin Alfa: A Review of its Pharmacodynamic and Pharmacokinetic Properties and Therapeutic Use In Nonrenal Applications", <i>Drugs</i> , Vol. 49 (2), pp. 232-254 (1995)
X5	C8	Egrie, et al., "Novel Erythropoiesis Stimulating Protein (NESP) has a longer Serum Half-life and greater <i>In vivo</i> Biological Activity Than Recombinant Human Erythropoietin (rHuEPO)", <i>Blood</i> , Vol. 90, pp. 56a, (1997)
X5	C9	MacDougall, et al., "Comparison of the Pharmacokinetics of Novel Erythropoiesis Stimulating Protein (NESP) and Epoetin Alfa (rhEPO) in Dialysis Patients", <i>Journal of the American Society of Nephrology</i> , Vol. 8, pp. 268A, (1997)
X5	C10	Creighton, et al., <i>Proteins, passim</i> (W.H. Freeman and Company, N.Y. 1984)
X5	C11	Ford, et al., "Fusion Tails for the Recovery and Purification of Recombinant Proteins", <i>Protein Expression and Purification</i> , Vol. 2, pp. 95-107, (1991)
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Date Considered:

10.10.03

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02-24-03

PATENT APPLICATION

1645

P#4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Tiansheng Li, et al.

Serial No.: 09/945,517

Group Art Unit No.: 1645

Filed: August 30, 2001

Examiner:

For: L-METHIONINE AS A STABILIZER FOR NESP/EPO IN  
HSA-FREE FORMULATIONS

Docket No.: A-803

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INFORMATION DISCLOSURE STATEMENT

FEB 27 2003

Assistant Commissioner for Patents  
Washington, D.C. 20231

TECH CENTER 1600/2900

Sir:

Under the guidelines of 37 C.F.R. 1.97, applicant(s) submit(s) a copy of (each of) the reference(s) listed on the attached supplemental PTO-1449 (Modified) form for consideration by the Examiner.

Applicant, by the undersigned attorney/agent, certifies that each item contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than 30 days pursuant to 37 C.F.R. 1.704(d) prior to the filing of this statement.

Applicant(s) request(s) consideration of this information and passage of the application to issue.

The Commissioner is hereby authorized to charge any additional fees, which may be required or credit any overpayment to Deposit Account No. 01-0519 in the name of Amgen Inc. An original and one copy of this paper are enclosed.

Please send all future correspondence to:

U.S. Patent Operations/RNM  
Dept. 4300, M/S 27-4-A  
AMGEN INC.  
One Amgen Center Drive  
Thousand Oaks, California 91320-1799

Respectfully submitted,

Randolph N. Mohr  
Attorney/Agent for Applicant(s)  
Registration No.: 45,590  
Phone: (805) 447-8949  
Date: February 20, 2003

## EXPRESS MAIL CERTIFICATE

Express Mail mail labeling number:

EL360692559US

Date of Deposit: February 20, 2003

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Printed Name

Signature

Modified Form PTO-1449

Atty. Docket No.

A-803

Serial No.

09/945,517

Applicant

Tiansheng Li, et al.

Filing Date

August 30, 2001

Group

1645

## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)



## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
KS	A18	4,835,260	May 30, 1989	Shoemaker			
HS	A19	5,929,028	July 27, 1999	Skrabanja, et al.			
XS	A20	US2002/0037841 A1 (USSN 09/853,731)	Mar 28, 2002	Papadimitriou			
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	A22						
	A23						
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	A25						
	A26						
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## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO
	B1					
	B2					
	B3					
	B4					
	B5					

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C1	
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*KM Sir*

Date Considered:

10-10-03

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